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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/362,731	07/29/1999	JEAN-MARIE SAINT-REMY	01699/P.UCB.	7229

7590 07/29/2002  
WENDEROTH LIND & PONACK LLP  
2033 K STREET N W SUITE 800  
WASHINGTON, DC 20006

EXAMINER

HUYNH, PHUONG N

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 07/29/2002

25

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action**

Application No.

09/362,731

Applicant(s)

SAINT-REMY ET AL.

Examiner

" Neon" Phuong Huynh

Art Unit

1644

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 02 July 2002 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**PERIOD FOR REPLY** [check either a) or b)]

- a) ☐ The period for reply expires \_\_\_\_\_ months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
- ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on 02 July 2002. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see Note below);
- (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_

3. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.
4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: None.Claim(s) objected to: None.Claim(s) rejected: 18, 25-28 and 30.Claim(s) withdrawn from consideration: 15 and 16.

8. ☐ The proposed drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_.
10. ☐ Other: \_\_\_\_\_

Continuation of 5. does NOT place the application in condition for allowance because:

The declaration by Jean-Marie Saint-Remy filed on June 17, 2002 is acknowledged.

Claims 18, 25-28 and 30 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated compound consisting of one of the following amino acid sequence selected from the group consisting of SEQ ID NO: 1, SEQ ID NO: 3, SEQ ID NO: 4 and SEQ ID NO: 5 for treating allergy against house dust mite (See page 22 line 25), does not reasonably provide enablement for (1) any isolated compound mentioned above for preventing or treating any allergy. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims for the same reasons set forth in Paper No 20.

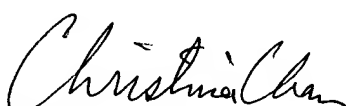
Applicants' arguments and the declaration by Jean-Marie Saint-Remy filed 6/17/02 have been fully considered but are not found persuasive.

Applicants' position is that claim 18 has been amended.

Although applicants have amended claim 18 to recite the specific compound selected from the specific SEQ ID NOS, newly added claim 30 recites the said compounds are use for preventing or treating any allergy. Given that the specific compounds are derived from house dust mite Der pII, neither the specification nor the declaration teaches the use any compounds mentioned above are effective for treating all allergy, let alone preventing.

The specification discloses only (1) a peptide consisting of SEQ ID NO: 2 which is a B cell epitope from Der pII (See page 23), (2) a peptide consisting of SEQ ID NO: 1 mixed with an adjuvant myramyl-dipeptide for immunization (page 25), (3) a peptide consisting of SEQ ID NO: 3 which contains a duplicate T cell epitope derived from tetanus toxoid linked to six repetitive B cell epitopes from Der pII (See page 25, example 2), (4) a peptide consisting of SEQ ID NO: 4 which contains B cell epitopes from Der pI and T cell epitopes from tetanus toxoid (See page 29), (6) a peptide consisting of SEQ ID NO: 5 which contains B cell epitopes from Der pII and T cell epitope from tetanus toxoid (page 29) for immunizing mice against house mite allergen (page 30-32) and (7) a prophetic teachings on the administration of said peptides using a humanized animal model SCID mice and a formulation for a cosmetic composition for skin hygiene on page 32, example 9.

The specification does not teach how to use any compounds mentioned above for preventing and treating all allergy. There is insufficient guidance and in vivo working examples that compounds derived from house mite are effective for all kinds of allergy. The term "prevents" is meant to warding off disease from happening. There is no showing in the specification that any of the claimed compounds can prevent any allergy. The state of the art does not teach immunizing a peptide from house dust mite would generate antibody that cross react with all allergen, in turn, would be useful for treating and preventing all allergy. In re wands, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988), the decision of the court indicates that the more unpredictable the area is, the more specific enablement is necessary. In view of the quantity of experimentation necessary, the limited working examples, the unpredictability of the art, the lack of sufficient guidance in the specification and the breadth of the claims, it would take an undue amount of experimentation for one skilled in the art to practice the claimed invention.

  
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